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MEMORANDUM

To: Jane DeMarchi
Vice President, Government and Regulatory Affairs, American Seed Trade Association

From: Maile Gradison Hermida
Partner, Hogan Lovells US LLP

Date: January 27, 2017

Re: **Update on FSMA Impacts for the Seed Industry**

This memorandum provides an update on implementation of the FDA Food Safety Modernization Act (FSMA) as it affects the seed industry. As discussed in more detail below, if seed companies are registered with FDA, they may be required to comply with the FSMA current Good Manufacturing Practice (GMP) and Hazard Analysis and Risk-Based Preventive Controls (PC) regulations. ASTA has been engaged in discussions with FDA on this issue for several years, advocating for exempting seed conditioning facilities from the FSMA regulations. As things currently stand, FDA's guidance is that facilities that shell corn, thresh soybeans, or chop corn husks that will be used as animal food would be required to comply with GMPs and PCs, but the remainder of seed facilities will be exempt. ASTA continues to engage in discussions with FDA on this issue and is submitting written comments in February.

Below we first explain the legal framework regarding how the seed industry fits within FSMA. Next, we discuss ASTA's engagement and dialog with FDA. Following, we explain the compliance dates. Finally, we summarize the developments and discuss next steps.

I. Legal Framework

Below we address the legal requirements for facility registration, GMPs, and preventive controls. We then explain the preventive controls exemption for "holding" raw agricultural commodities and FDA's draft guidance addressing the scope of this exemption.

A. Facility Registration

A facility is required to register with FDA if it manufactures, processes, packs, or holds food for human or animal consumption in the United States. 1/ FDA has long taken the position that an establishment that conditions seed is required to register with FDA if it reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. The agency recently updated its draft guidance on this point, which

1/ 21 C.F.R. § 1.225.

continues to take the same position but includes some changes in the wording. 2/ The revised draft guidance states:

> [Q.] Is an establishment that conditions seed and sells seed to farmers for cultivation a facility that is required to register if some of the seed sold is intended to be used as animal food?
>
> [A.] A facility that manufactures/processes, packs, or holds food for consumption in the United States is required to register. "Food" is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) to include articles used for food or drink for man or other animals. An establishment that conditions and sells seed to farmers for planting purposes is typically excluded from the requirements for registration. However, an establishment that conditions seed for planting purposes is a facility that must be registered if the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. Whether a particular establishment is required to register will depend on the specific nature of the establishment. This would include situations where seeds are sent for use as animal food because they become cracked, damaged, culled, or are otherwise not suitable for cultivation. However, some establishments may direct such cracked, damaged, culled, or excess seeds for incineration and landfilling. If the seed is reasonably expected only to be cultivated or destroyed (e.g., by incineration or landfill), the establishment is not required to register. (See Comment 3 in the Registration Final Rule; 81 FR 45912 at 45919). 3/

Thus, seed facilities that "reasonably believe" that unplantable seeds will be directed for animal consumption are expected to register with FDA.

Facilities that are required to register with FDA (i.e., facilities that manufacture, process, pack, or hold food for human or animal consumption) are required to comply with the FSMA regulations addressing Preventive Controls for Human Food (PCHF) and/or Preventive Controls for Animal Food (PCAF), as applicable, unless an exception applies. 4/

B. GMPs and Preventive Controls

The PCHF and PCAF regulations each have two components: GMPs and PCs. The GMP regulations are focused on foundational food safety programs. They address issues such sanitation, water supply and plumbing, equipment and utensils, and plant operations. The regulations are general performance standards that are applied flexibly depending on the type of food and facility. An example of a typical GMP is: "Buildings, structures, fixtures, and other facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated." 5/ Although GMPs have applied to human food manufacturers for many years, the FSMA regulation is the first application of GMPs for the animal food industry. The GMP regulations for animal food are codified in 21 CFR Part 507, Subpart B.

2/ This position also was reaffirmed in FDA's regulation amending the facility registration requirements. 81 Fed. Reg. 45912, 45919 (July 14, 2016).

3/ *Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry*; Draft Guidance; December 2016 at B.1.2; *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf

4/ 80 Fed. Reg. 56170 (Sept. 17, 2015) (PCAF); 80 Fed. Reg. 55908 (Sept. 17, 2015) (PCHF). Note that a facility that is in compliance with the PCAF regulation is deemed in compliance with the PCHF regulation. 21 C.F.R. § 507.1(d).

5/ 21 C.F.R. § 507.19(a).

The preventive controls requirements are much more expanisve than GMPs. The regulation requires every facility to conduct a hazard analysis to identify and evaluate known or reasonably foreseeable biological, chemical, and physical hazards for each type of animal food manufactured, processed, packed, or held at the facility. If any hazards are determined to be "hazards requiring a preventive control," the facility must identify and implement preventive controls that will significantly minimize or prevent the hazards. Examples of preventative controls are process controls (e.g., heat processing), sanitation controls (e.g., to prevent cross-contamination), and supply chain controls (e.g., confirming that your supplier managed a hazard). Preventive controls are subject to "management components" that must be applied to ensure the preventive controls are effective. These management components are monitoring, corrective actions, and verification. Facilities also must validate certain types of preventive controls, implement a supplier verification program for any hazards controlled upstream, reanalyze their food safety plan at least every 3 years, and develop a recall plan. All required activities must be documented in records that are available for inspection by FDA. The PC regulations for animal food are codified in 21 CFR Part 507, Subpart C (preventive controls) and Subpart E (supply-chain program).

C. Preventive Controls Exemptions for "Holding" Food

The PCAF final rule exempts facilities from compliance with Subparts C (preventive controls) and E (supply-chain program) if they are "solely engaged in the storage of [raw agricultural commodities (RACs)] (other than fruits and vegetables) intended for further distribution or processing." 6/ Additionally, the PCAF rule exempts facilities from Subpart B (GMPs) if they are "solely engaged in the holding and/or transportation of one or more RACs." 7/

"Holding" is defined in 21 CFR § 507.3 as

> storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid-storage tanks. 8/

ASTA's efforts have been focused on ensuring that the activities performed by seed facilities fit within the scope of these two "solely engaged" in holding provisions. 9/

D. Definition of "Holding"

In August 2016, FDA issued draft guidance entitled *Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities*. 10/ The draft guidance

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6/ 21 C.F.R. § 507.5(g). There is a parallel exemption in the PCHF regulation. 21 C.F.R. § 117.5(j).

7/ 21 C.F.R. § 507.5(h)(1). There is a parallel exemption in the PCHF regulation. 21 C.F.R. § 117.5(k)(iii).

8/ "Holding" and "storage" are synonyms under the rule.

9/ If a facility is exempt from PCAF under the approach ASTA is pursuing, it also would be exempt from PCHF because the human and animal food regulations provide parallel exemptions.

addresses whether given activities meet the legal definitions of harvesting, packing, holding, or manufacturing/processing. The agency explains that the draft guidance is, in part, intended for companies that need to determine whether they are exempt from preventive controls and GMPs under the "solely engaged" in holding provisions in 21 CFR §§ 507.5(g) and 507.5(h)(1). To make this determination, a facility that is engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing needs to determine whether all the activities it performs fall within the definition of "holding."

The draft guidance provides additional examples of activities that can be classified as "holding," beyond those included in the regulation itself and accompanying preamble. The draft guidance explains that an activity can constitute holding because it is (1) performed for the safe or effective storage of food or (2) performed as a practical necessity for the distribution of a food. On the second point, FDA emphasizes that "activities performed as practical necessity for distribution of a food" are limited to only those activities that are truly necessary, as a practical matter, to any holding and distribution of the food in question. Activities optionally performed to add value to a food cannot be considered "holding" on this basis. Also, any activity that changes a RAC into processed food is expressly excluded from "holding."

The draft guidance specifically provides that shelling and removing or trimming parts of RACs are not "holding" activities. The guidance goes on to explain that shelling and chopping are examples of "manufacturing/processing" activities. This is relevant because if a facility engages in any manufacturing/processing activities, it cannot be considered to be "solely engaged" in holding animal food, so it would be subject to GMPs and PCs.

II. ASTA's Engagement with FDA

ASTA has submitted multiple comments to FDA and has met several times with key agency personnel. ASTA's focus has been on establishing seed facilities as exempt from the PCAF final rule on the basis that their activities all constitute "holding." As discussed above, a facility that is "solely engaged" in holding raw agricultural commodities is not required to comply with good manufacturing practices GMPs or preventive controls under the PCAF regulation.

In February 2016, ASTA held a meeting with senior personnel in FDA's Center for Veterinary Medicine (CVM) to discuss how seed facilities are regulated under FSMA. FDA said that their intent is to exempt seed facilities from the PCAF final rule on the basis that their activities all constitute "holding." The agency pointed to the following statement in the PCAF supplemental proposed rule addressing seed facilities and said that this statement is the agency's signal that the industry can fall within this exemption:

> With this revised definition of 'holding,' facilities such as grain elevators and silos would, in most cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 507.5(g)), because the definition would encompass activities performed as a practical necessity for the distribution of RACs. Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as facilities that package and sell seed for crops, but sell the leftover seed for animal food, also may satisfy these criteria for exemption. 11/

10/ Available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517575.pdf

11/ 79 Fed. Reg. 58746, 58484 (Sept. 29, 2014).

The agency also explained that on this basis, inspection of the seed industry is not a priority.

At CVM's recommendation, following the meeting we submitted several questions to FDA's Technical Assistance Network (TAN) to receive confirmation that seed facility activities are classified as "holding." 12/ We received generally positive feedback from the TAN in mid-2016 recognizing that the majority of the activities performed by seed conditioning facilities fall within the scope of "holding." However, the agency took the position in the TAN response that removing seeds from the cob (shelling) and removing soybeans from the pod (threshing) are manufacturing/processing activities. The agency took the same position in the August 2016 draft guidance on activity classification, as discussed above. 13/

In November 2016, ASTA met again with key personnel at FDA. This meeting included representatives from both CVM and the Center for Food Safety and Applied Nutrition (CFSAN), which was notable because the activity classification guidance and TAN responses on shelling/threshing came from CFSAN. The outcome of the meeting was disappointing because FDA continued to take a hardline related to corn shelling and soybean threshing being manufacturing activities. The agency also said that husk chopping could be a manufacturing activity. The agency was not swayed by arguments that their approach is not risk-based, given that the same activity could be exempt if conducted in the field. Instead, the agency felt constrained by their interpretation of the legal framework and took the view that a facility engaging in these activities is doing more than is necessary for (1) the safe or effective storage of food or (2) as a practical necessity for the distribution of a food.

On a positive note, in the November 2016 meeting FDA reiterated their position that they are not targeting seed facilities for inspections in fiscal year 2017. However, seed facilities could be inspected by state regulators and some ASTA members have reported such inspections in 2017.

III. Compliance Dates

The compliance dates for animal food GMPs and preventive controls are:

Size of Business	**cGMP Compliance Date**	**Preventive Controls Compliance Date** 14/
500+ full-time equivalent (FTE) employees	September 19, 2016	September 18, 2017
Under 500 FTE employees (small businesses)	September 18, 2017	September 17, 2018
Less than $2.5 million in annual sales/holding value of animal food (very small businesses)	September 17, 2018	September 17, 2019

12/ We identified that seed conditioning facilities engage in the following activities: drying, blending, weighing, sampling and grading, fumigating to control pest infestation during storage, cleaning (e.g., sifting, sieving, and screening), conveying, sorting, removing materials (e.g., stems, leaves, and husks), removing corn seeds from the cob (shelling), removing soybeans from the pod (threshing), chopping husks (to decrease their size and bulk for shipping), hulling, and moisturizing large vegetable seed.

13/ The draft guidance identified threshing as a harvesting activity when performed on the farm. It did not specifically address whether threshing is "holding," but we understand that this is the agency's intent based on the TAN responses.

14/ There are later compliance dates for supplier verification for some smaller suppliers. Supplier verification is only required if a supplier is controlling a "hazard requiring a preventive control."

IV. Modified Requirements for "Very Small Businesses" with Sales under $2.5 million

There are modified preventive controls compliance requirements for very small businesses (also known as "qualified facilities"). 15/ These facilities must submit attestations to FDA regarding their status as a qualified facility and affirming that either (1) they have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls, or (2) they are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law.

The regulatory definition of "very small business" for this purpose is "a business (including any subsidiaries and affiliates) averaging less than US $2,500,000 adjusted for inflation, per year, during the 3-year-period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)." 16/ Thus, animal food that is distributed but not "sold" or supplied to a farm without sale must be included in determining whether a facility is a very small business. Additionally, the threshold dollar amount must consider global sales—not just sales within the United States. However, the dollar amount does not consider sales of seed for planting. 17/ FDA explained in the preamble that this exemption is not intended to apply for large, sophisticated businesses.

V. Discussion and Next Steps

Based on the position FDA is currently taking about the narrow definition of "holding," the seed industry now finds itself in a situation where seed facilities could be regulated differently depending on the crop of seed being produced. Corn seed facilities and soybean research facilities typically remove seeds from the cob/pod and therefore would be considered to be engaging in manufacturing. Likewise, facilities that send husks for animal consumption and chop them before doing so would be considered to be manufacturing. The remainder of the industry would be exempt because all of their activities fall within the definition of "holding."

It is important to bear in mind, however, that FDA's approach in the draft guidance (and TAN responses) is **non-binding**. Draft guidance is distributed for comment purposes only. 18/ Companies can take the position that their activities all fall within the scope of "holding" such that they are exempt from both GMPs and Preventive Controls, but they face the potential that FDA could disagree with this position. As it currently stands, FDA has explained that its position is that shelling corn, threshing soybeans, or chopping husks do not fall within the definition of "holding."

ASTA is continuing to actively engage with FDA on these issues. There are currently two public comment periods open and ASTA plans to submit comments by the following deadlines:

- February 21, 2017: Classification of activities draft guidance.
- March 27, 2017: Facility registration draft guidance.

It will take FDA some time thereafter (perhaps over a year) before FDA finalizes the guidance. Consequently, FDA and state investigators likely will be trained based on the current interpretations in the draft guidance.

15/ 21 C.F.R. § 507.7.
16/ 21 C.F.R. § 507.3.
17/ 80 Fed. Reg. at 56170, 56203 (Sept. 17, 2015)
18/ The draft guidance states: "This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration[] on this topic. It does not establish any rights for any person and is not binding on FDA or the public."

FDA has signaled that seed facilities are unlikely to be inspected in fiscal year 2017 (unless a known problem arises). However, seed facilities could be inspected by state regulators and some ASTA members have reported such inspections in 2017. Currently, inspections are only focused on GMPs because the earliest compliance date for preventive controls is not until September 2017 and only applies to companies with over 500 FTE employees.

In summary, ASTA is disappointed with FDA's current position but will continue to strongly advocate for the industry's position that all seed facilities should be exempt from the FSMA regulations. It is notable that the agency's current position was under the Obama Administration, and there may be a renewed opportunity to affect the agency's approach under the Trump Administration. Accordingly, ASTA also is considering legislative options.

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Should you have any questions, please do not hesitate to contact us.